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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,644	11/26/2008	John P. Toscano III	P30955US02/20642.034	2708

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EXAMINER	
THOMAS, TIMOTHY P	

ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
04/11/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IP.Docketing@aporter.com

Office Action Summary	Application No.	Applicant(s)	
	10/587,644	TOSCANO ET AL.	
	Examiner	Art Unit	
	TIMOTHY THOMAS	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,15,49,50 and 53* is/are pending in the application.

5a) Of the above claim(s) *49 and 50* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,15 and 53* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/26/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/26/2011 has been entered.

Election/Restrictions

2. The elected species under examination is the compound of claim 1, where both R^1 and R^2 are $-CH_2CF_3$. This elected compound also reads on newly presented claim 53, which is under examination.

3. Claims 1, 15 and 53 are under examination, as reading on the elected compound.

4. Claims 49-50 remain withdrawn.

Response to Arguments

5. Applicant's arguments with respect to the obviousness rejection have been fully considered but they are not persuasive:

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

> said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

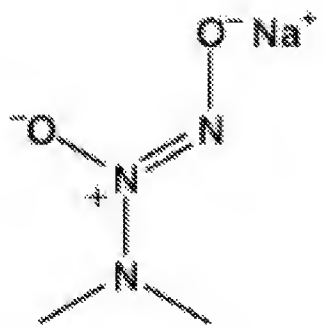
Claims 1, 15 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitzhugh et al. ("Qualitative Thin-Layer and High-Performance Liquid Chromatographic Analysis of 1-Substituted Diazen-1-ium-1,2-diolates on Aminopropyl-Bonded Silica Gel"; 2002; Analytical Biochemistry; 301: 97-102; IDS 3/26/2010 reference BJ1); in view of Patani et al. ("Bioisosterism: A Rational Approach in Drug Design"; 1996; Chem. Rev.; 96: 3147-3176) and Ismail

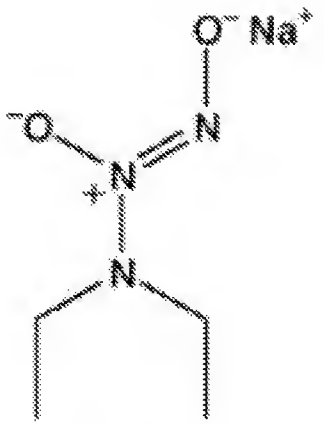
("Important fluorinated drugs in experimental and clinical use"; 2002; Journal of Fluorine Chemistry; 118: 27-33).

The rejection is maintained with respect to claims 1 and 15, for the reasons of record. The same reasons, which are based on the elected compound, are also applicable to the subject matter of the elected compound, within the scope of claims 53. This claim, drawn to the same elected compound as claims 1 and 15, present before the request for continued examination, could also have been rejected on the same basis, if this claim had been presented before the final Office Action mailed 2/28/2011. Accordingly, per MPEP 706.07(b), this action can be made final (see below).

The record establishes:

Fitzhugh teaches diazeniumdiolates, compounds containing the anionic $R_2N[N(O)NO]^-$ moiety, are receiving increasing use as nitric oxide (NO) donors in chemical and biochemical studies; the release of NO in such settings produces pharmacological effects including cytostasis, vasodilation, penile erection, etc.; these remarkable properties have generated considerable interest in the potential further use of diazeniumdiolates as therapeutic agents, particularly in the treatment of such important clinical disorders as pulmonary hypertension, cerebral vasospasm, impotence and thrombosis at blood-contact surfaces (p. 97, 1st paragraph). Compounds specifically taught include:



1 and 

2 (p. 99, Fig. 2).

Compounds 1 and 2 are each salts of formula (I), i.e., a compound of formula (I), where n and m are 0, R^1 and R^2 are each alkyl (methyl for compound 1, ethyl for compound 2), reading on each of the instant claims.

Fitzhugh does not specifically teach the elected compound, although this compound would be within the scope of the genus of diazeniumdiolates, compounds containing the anionic $R_2N[N(O)NO]^-$ moiety, taught by Fitzhugh.

Patani teaches a lead compound with a desired pharmacological activity may have associated with it undesirable side effects, characteristics that limit its bioavailability, or structural features which adversely influence its metabolism and excretion from the body; bioisosterism represents one approach used by the medicinal chemist for the rational modification of lead compounds into safer and more clinically effective agents (p. 3147, 1st paragraph); the ability of a group of bioisosteres to elicit similar biological activity has been attributed to common physicochemical properties, such as electronegativity, steric size and lipophilicity; values are correlated to biological activity (p. 3148, 2nd paragraph). Classical

bioisosteres include the substitution of hydrogen by fluorine, which is one of the more commonly employed monovalent isosteric replacements; steric parameters for hydrogen and fluorine are similar, the difference in the electronic effects is often the basis for the major differences in the pharmacological properties of agents where fluorine has been substituted for hydrogen (p. 3149, 5th paragraph). This reference provides motivation to substitute F for H in an active compound in an attempt to find a safer and/or more effective agent than the starting compound.

Ismail teaches fluorine imparts desirable characteristics to drugs by modulating both the pharmacokinetics and pharmacodynamic properties of a drug; incorporation of fluorine into a drug increases the lipophilicity enhancing absorption into biological membranes whereby its small covalent radius can facilitate docking with their drug receptor(s) (abstract); bioisosteric substitution of hydrogen by fluorine is, therefore, an important strategy for incorporation of a group capable of reinforcing drug-receptor interactions, aiding translocation across lipid bilayers or absorption (p. 27, 2nd paragraph). Specific groups taught in molecules include trifluoromethyl groups (p. 28, right, 2nd paragraph; see also examples in compounds (8), which has two trifluoromethyl moieties and (9) (p. 28). This reference provides motivation to utilize trifluoromethyl groups in active compounds for the purposes taught by Ismail.

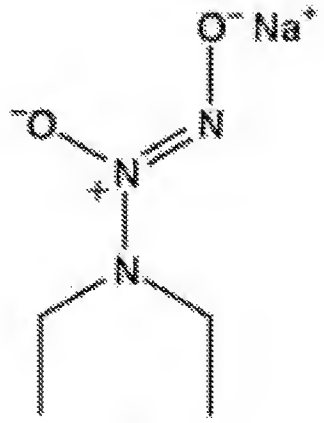
It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute the terminal methyl hydrogens of the ethyl moieties of compound 2 taught by Fitzhugh, with fluorine atoms to give

trifluoromethyl moieties, where the R groups of the diazeniumdiolate compound corresponds to $-CH_2CF_3$, i.e., the instant elected compound. The motivation would have been the expectation of increased lipophilicity enhancing absorption and/or improved translocation across membranes to a target location.

The record also establishes:

With respect to the statement made in *Sanofi* that a *prima face* case of obviousness depends on whether the prior art provides a suggestion or reason to choose a specific lead compound for modification, such a suggestion and reason to select compound 2, based on the teachings of Fitzhugh, is of record. The record indicates that Fitzhugh teaches:

> diazeniumdiolates, compounds containing the anionic $R_2N[N(O)NO]^-$ moiety, are receiving increasing use as nitric oxide (NO) donors in chemical and biochemical studies; the release of NO in such settings produces pharmacological effects including cytostasis, vasodilation, penile erection, etc.; these remarkable properties have generated considerable interest in the potential further use of diazeniumdiolates as therapeutic agents, particularly in the treatment of such important clinical disorders as pulmonary hypertension, cerebral vasospasm, impotence and thrombosis at blood-contact surfaces (p. 97, 1st paragraph). Compounds specifically taught include: …



2

This teaching establishes the Fitzhugh compounds are nitric oxide donors in chemical and biochemical studies; that release of NO provides pharmacological effects, including cytostasis, vasodilation, penile erection, etc; that the compounds have considerable interest in potential further use as therapeutic agents, in treatment of pulmonary hypertension, cerebral vasospasm, impotence and thrombosis at blood-contact surfaces. These biological properties and potential therapeutic applications, which provide suggestion for selection and provide a reason to select the Fitzhugh compounds, are an articulated rationale by Fitzhugh for selection of any one of the 7 compounds specifically taught by Fitzhugh, including compound 2, as a "lead compound", for further modification.

The record has also established a line of reasoning that would have led one of ordinary skill in the art to modify a prior art lead compound in a particular way to produce the claimed compound. The record indicates Patani teaches:

> Classical bioisosteres include the substitution of hydrogen by fluorine, which is one of the more commonly employed monovalent isosteric

replacement; steric parameters for hydrogen and fluorine are similar, the difference in the electronic effects is often the basis for the major differences in the pharmacological properties of agents where fluorine has been substituted for hydrogen (p. 3149, 5th paragraph). This reference provides motivation to substitute F for H in an active compound in an attempt to find a safer and/or more effective agent than the starting compound.

The record also indicates Ismail teaches:

fluorine imparts desirable characteristics to drugs by modulating both the pharmacokinetics and pharmacodynamic properties of a drug; incorporation of fluorine into a drug increases the lipophilicity enhancing absorption into biological membranes whereby its small covalent radius can facilitate docking with their drug receptor(s) (abstract); bioisosteric substitution of hydrogen by fluorine is, therefore, an important strategy for incorporation of a group capable of reinforcing drug-receptor interactions, aiding translocation across lipid bilayers or absorption (p. 27, 2nd paragraph). Specific groups taught in molecules include trifluoromethyl groups (p. 28, right, 2nd paragraph; see also examples in compounds (8), which has two trifluoromethyl moieties and (9) (p. 28). This reference provides motivation to utilize trifluoromethyl groups in active compounds for the purposes taught by Ismail.

The motivation of record indicates:

> It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute the terminal methyl hydrogens of the ethyl moieties of compound 2 taught by Fitzhugh, with fluorine atoms to give trifluoromethyl moieties, where the R groups of the diazeniumdiolate compound corresponds to $-CH_2CF_3$, i.e., the instant elected compound. The motivation would have been the expectation of increased lipophilicity enhancing absorption and/or improved translocation across membranes to a target location.

Therefore, the requirement of *Altana* to establish a line of reasoning that would have led one of ordinary skill in the art to select and modify a prior art lead compound in a particular way to produce the claimed compound has been met.

Applicant argues:

> The evidence and arguments of record fail to establish a prima facie case of obviousness. A "prima facie case depends on whether the prior art provided a suggestion or reason to choose a specific lead compound for modification, or to make the specific modification of the compound at issue." *Sanofi-Synthelabo v. Apotex*, 550 F.3d 1075 (Fed. Cir. 2008); cert. petition filed, 78 USLW 3065 (Jul 24, 2009), quoting *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007); see also, *Procter & Gamble Co. v. Teva Pharmaceuticals USA Inc.*, 556 F.3d 989 (Fed. Cir. 2009); and *Eisai Co. v. Dr. Reddy's Laboratories, Ltd.*, 553 F.3d 1353, 1358 (Fed. Cir. 2008). Neither Fitzhugh

> et al., Patani et al. nor Ismail teaches or suggests either the specific lead compound or the specific structural modifications that are necessary to make applicants' claimed compounds.

This is not persuasive. Fitzhugh teaches 7 nitric oxide donor compounds, which specifically include compound 2. The selection of this compound would have been obvious, simply based on the reasons given in the article; as previously established:

> the Fitzhugh compounds are nitric oxide donors in chemical and biochemical studies; that release of NO provides pharmacological effects, including cytostasis, vasodilation, penile erection, etc; that the compounds have considerable interest in potential further use as therapeutic agents, in treatment of pulmonary hypertension, cerebral vasospasm, impotence and thrombosis at blood-contact surfaces. These biological properties and potential therapeutic applications, which provide suggestion for selection and provide a reason to select the Fitzhugh compounds, are an articulated rationale by Fitzhugh for selection of any one of the 7 compounds specifically taught by Fitzhugh, including compound 2, as a "lead compound", for further modification.

Thus, an articulated rationale for selection of compound 2 is of record.

Additionally, applicant is referred to the Federal Register Notice regarding "Examination Guidelines Update: Developments in the Obviousness Inquiry After KSR v. Teleflex" (Federal Register; Vol. 75, No. 169; 9/1/2010; pp. 53643-53660). On p. 53652, left column, 2nd paragraph, the Office makes clear the

policy regarding selection of a "lead compound" in order to support an obviousness rationale. Example 4.12 of the notice states:

> *Example 4.12. Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, 566 F.3d 989 (Fed. Cir. 2009). *Teaching point:* It is not necessary to select a single compound as a "lead compound" in order to support an obviousness rejection. However, where there was reason to select and modify the lead compound to obtain the claimed compound, but no reasonable expectation of success, the claimed compound would not have been obvious.

Thus, Proctor & Gamble v. Teva establishes **it is not necessary to select a single compound as a lead compound to support an obviousness rejection**. In view of current Office policy, applicant's argument that an articulated rationale for selection of compound 2 has not been made, is not relevant.

Applicant further argues that in contrast to *Altana*, the evidence of record fails to show that any of Fitzhugh's diazeniumdiolates is either potent, and improvement over the prior art, or even particularly effective as an NO donors or a therapeutic agent such as to warrant further development efforts. No such showing is required. Applicant is again referred to Example 4.12 of the Federal Register notice, as discussed above.

Applicant argues that at the time of applicants' invention, one of ordinary skill in the art would have known that diazeniumdiolates derived from secondary amines were highly unstable with very short half-lives, making reference to Hrabie and Cao articles, cited in the 7/26/2011 IDS. Review of Cao, for example, indicates that Cao does not disparage compounds with short half-lives, but appears to prefer them; i.e., because they give the "strongest effects" with respect to DA uptake. Cao indicates (p. 1157, right, top paragraph):

> Various diazeniumdiolates and 3-morpholynosydnonimine (SIN-1), with half-lives ranging from 2 min to 20 h (Zamora *et al.*, 1997; Fitzhugh & Keefer, 2000; Babich & Zuckerbraun, 2001), were tested for their effect on [^{3}H]-DA uptake (Figure 2). Diethylenetriamine (DETA)/NO ($t_{1/2}$, 20 h) and dipropylenetriamine (DPTA)/NO ($t_{1/2}$, 5 h) were ineffective over the entire concentration range. Spermine (SPER)/NO ($t_{1/2}$, 0.5 - 2.3 h) displayed some uptake inhibitory activity at the highest concentration tested (0.8 mM), whereas the strongest effects were observed for PAPA/NO ($t_{1/2}$, 15 min), DEA/NO ($t_{1/2}$, 2 min), and SIN-1 ($t_{1/2}$, 10 min).

Thus, the point of shorter half-lives has not been established as a teaching away from modification of compound 2 of Fitzhugh.

Additionally, a brief review of the state of the art, with regards to short half-life NO compounds, found that the well-known compound nitroglycerin, used for treatment of angina pectoris and other acute heart conditions, has a half-life of only 1.9 minutes (See Armstong, et al.; "Pharmacokinetic-hemodynamic studies of intravenous nitroglycerin in congestive cardiac failure"; 1980; Circulation; 62:160-166; p. 163, Figure 3.) Nitroglycerin, with a very short half-life, i.e., nearly the same as compound 2 of Fitzhugh, has clear therapeutic efficacy in a series of heart conditions, including angina pectoris, myocardial infarction and congestive

cardiac failure. Compound 2 would also have been expected to have clear usefulness in the same type diseases. Thus, a short half-life can actually be a preferable characteristic for acute therapy, as opposed to a teaching away.

Applicant argues in light of compound 2's instability, one of ordinary skill in the art would not have been motivated to improve compound 2's pharmacokinetic or phamacodynamic properties, whether by fluorination or other means. As discussed above, with respect to nitroglycerin, a 2 minute half-life clearly has clear therapeutic utility, and appears to be preferable for some purposes, not a teaching away from further modification of this compound. Additionally, motivation to modify this compound has been established on the record:

> Identifying some line of reasoning that would have led one of ordinary skill in the art to select and modify a prior art lead compound in a particular way to produce the claimed compound, has been established. It is further noted that Patani indicates the F/H substitution is one of the more commonly employed monovalent isosteric replacements; and Ismail, which is primarily concerned with fluorine substitution, teaches fluorine imparts desirable characteristics to drugs by modulating both the pharmacokinetics and pharmacodynamic properties of a drug; incorporation of fluorine into a drug increases the lipophilicity enhancing absorption into biological membranes whereby its small covalent radius can facilitate docking with their drug receptor(s); Ismail clearly gives the examples of bioisosteres having a single trifluoromethyl and even two

separate trifluoromethyl groups in the same compound, rendering the specific modification obvious.

Applicant further argues Patani teaches a broad range of functional groups, including monovalent groups, divalent groups, trivalent groups, tetravalent groups, ring equivalents, cyclic or non-cyclic non-classical replacements and non-classical replacements of functional groups; and that the extensive list is by no means exhaustive; that many of the bioisosteric replacements have potential drawbacks; fluoro substitution can lead to "loss of potency", trifluoromethyl substitution can decrease biological activity or cause adverse reactions; that in view of the various tools available for rational drug design and the potential disadvantages of bioisosteric replacement, particularly fluoro and trifluoromethyl substitution, it is unclear how an ordinary skilled artisan would have singled out fluorine replacement as the sole means for modifying Fitzhugh's compounds.

The rejection basis does not assume trifluoromethyl or fluoro replacement is some "sole means"; there are clearly other ways in which Fitzhugh's compounds could be modified. However, the basis of record establishes a rationale to arrive at applicant elected compound, based on the motivation of an expectation of increasing lipophilicity, enhancing absorption and/or improved translocation across membranes to a target location. The potential benefit is clearly established by Patani: i.e., that this reference provides motivation to substitute F for H in an active compound in an attempt to find a safer and/or more effective agent than the starting compound.

The Court of Appeals for the Federal Circuit has looked favorably upon the Office's use of bioisosterism as a basis for rejection of claims to new chemical compounds. See, e.g., *In re Merck & Co., Inc.*, 231 USPQ 375, 800 F2d 1091 (Fed. Cir. 1986), which states that:

> [s]tructural similarity, alone, may be sufficient to give rise to an expectation that compounds similar in structure will have similar properties. ... [I]n attempting to predict the biological activities of a drug, a skilled medicinal chemist would not proceed randomly, but would base his attempts on the available knowledge of prior research techniques, and literature used in his field. The prior art showed that one such technique was "bioisosteric replacement" or the theory of bioisosterism -- where the substitution of one atom or group of atoms for another atom or group of atoms having similar size, shape and electron density provides molecules having the same type of biological activity. Finding that the [prior art] references taught that bioisosterism was commonly used by medicinal chemists ... in an effort to design and predict drug activity, ... one of ordinary skill in the arts would have been aware of this technique at the time of ... invention.

Merck, 231 USPQ at 379 (internal citations omitted).

The position is maintained that the substitution of the trifluro methyl moiety for the terminal methyl of compound 2, to give the elected compound, would have been expected to yield a compound with similar biological activity, with the potential for a safer and/or more effective therapeutic agent from the prior art compound 2 taught by Fitzhugh. Such bioisoteric replacements are commonly used by medicinal chemists as a rational modification of lead compounds into safer and more clinically effective agents, thus, rendering the use of this approach as a modification of compound 2 of Fitzhugh, to give the elected compound as *prima facie* obvious.

Conclusion

9. No claim is allowed

10. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Primary Examiner, Art Unit 1628